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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,602	03/01/2002	Matthew Patricelli	063391-0302	7925
30542	7590	07/13/2004	EXAMINER	
FOLEY & LARDNER			COUNTS, GARY W	
P.O. BOX 80278			ART UNIT	
SAN DIEGO, CA 92138-0278			PAPER NUMBER	

1641

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,602

Applicant(s)

PATRICELLI, MATTHEW

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/01/02.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-5 and 48, drawn to a method for determining the presence in a complex protein mixture, classified in class 436, subclass 518.
 - II. Claims 6-13, 16 and 48, drawn to a method for determining the presence in a complex protein mixture, classified in class 210, subclass 656.
 - III. Claims 14, 15 and 48, drawn to a method for determining the presence in a complex protein mixture, classified in class 436, subclass 173.
 - IV. Claims 17-19 and 48, drawn to a method for determining the presence in a complex protein mixture, classified in class 204, subclass 450.
 - V. Claim 20, drawn to a kit, classified in class 435, subclass 810.
 - VI. Claims 21-32 and 48, drawn to a method for determining the presence, amount, or activity of one or more active target proteins, classified in class 435, subclass 7.1.
 - VII. Claims 33-44 and 48, drawn to a method for comparing the presence, amount, or activity of one or more active target proteins, classified in class 435, subclass 973.
 - VIII. Claims 45-47, drawn to a method of correlating a separation profile to a peptide having a known sequence, classified in class 435, subclass 527.
2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. Invention II requires a second control complex and second probe wherein the first and second probe compositions differ in having independently detectable labels and Invention I does not require these limitations. Also, Invention I requires mass spectrometry and Invention II does not require this limitation. Invention II requires a washing step and Invention I does not require this limitation.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Invention I requires proteolytically digesting conjugates and Invention III does not require this limitation. Invention III requires second control complex and second probe composition and the first and second probe compositions differ in their isotopic labeling and Invention I does not require these limitations.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the inventions are not disclosed as capable of use together and they have different modes of operation. Invention IV involves a

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protease bound to a solid surface and Invention I does not require this limitation.

Further, Invention I involves the limitation for mass spectrometry the ion peaks indicate the presence of the target protein and Invention IV does not require this limitation.

5. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions II or III.

6. Inventions I and VI are independent and distinct. Invention I requires sequestering the conjugates with a solid support to which is bound receptor for the ligand and Invention VI does not require this limitation. Further, Invention I requires electrophoretic separation or mass spectrometry based on the different migration rates of the fragment conjugates using the label to detect the fragment conjugates or for mass spectrometry based on ion peaks and Invention VI does not require these limitations.

7. Inventions I and VII are independent and distinct inventions. Invention I requires that the elution or migration rate of the fragment conjugates indicates the presence of the target protein and/or for mass spectrometry the ion peaks indicate the presence of the target protein and Invention VII does not require these limitations. Invention VII requires contacting a second complex protein mixture with a second activity based probe and Invention I does not require this limitation.

8. Inventions I and VIII are independent and distinct inventions. Invention I requires steps of proteolytically digesting the conjugates, releasing the fragment conjugates and sequestering with a solid support and Invention VIII does not require these limitations. Also, Invention VIII requires a peptide to have a known sequence and Invention I does not require this limitation.

9. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions are not disclosed as capable of use together and they have different modes of operation. Invention II requires proteolytically digesting proteins at a time prior to releasing and Invention III does not require this limitation. Invention III requires mass spectrometry and Invention II does not. Invention II requires isotopically labeled probes and Invention III does not require these limitations.

10. Inventions II and IV are independent and distinct inventions. Invention IV requires combining the conjugates with at least one protease bound to a solid surface and Invention II does not require this limitation. Invention II requires second control complex protein mixture with a second probe composition and Invention IV does not require this limitation.

11. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions I or III.

12. Inventions II and VI are independent and distinct inventions. Invention II requires Invention II requires second control complex protein mixture with a second probe composition and Invention VI does not require this limitation.

13. Inventions II and VII are independent and distinct inventions. Invention II requires a washing step and invention VII does not require this limitation. Invention II requires enriching released conjugate components by separating conjugates by at least one of liquid chromatography and electrophoresis with detection of conjugates by means of detectable probe and Invention VII does not require these limitations. Invention II requires characterizing the conjugates by their migration rates in the enriching step and Invention VII does not require this limitation.

14. Inventions II and VIII are independent and distinct inventions. Invention II involves a second control complex protein mixture and a second probe composition and Invention VIII does not require this limitation. Invention VIII involves a separation profile and Invention II does not require this limitation. Also Invention II involves washing, proteolytically digesting and enriching released conjugate components and Invention VIII does not require these limitations.

15. Inventions III and IV are independent and distinct inventions. Invention III involves a second control complex protein mixture with a second probe composition and isotopically labeled probe and Invention IV does not require these limitations. Invention

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IV involves at least one protease bound to a solid surface and Invention III does not require this limitation.

16. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions I or II.

17. Inventions III and VI are independent and distinct inventions. Invention III involves a second control complex protein mixture with a second probe composition and isotopically labeled probe and Invention VI does not require these limitations. Invention VI involves proteolyzing the active target proteins and Invention III does not require this limitation.

18. Inventions III and VII are independent and distinct inventions. Invention III involves an isotopically labeled probe and Invention VII does not require this limitation. Invention VII involves proteolyzing the active target proteins and Invention III does not require this limitation.

19. Inventions III and VIII are independent and distinct inventions. Invention III involves an isotopically labeled probe and Invention VIII does not require this limitation. Invention VIII involves generating a separation profile and Invention III does not require this limitation.

20. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions I or II.

21. Inventions IV and VI are independent and distinct inventions. Invention IV requires at least one protease bound to a solid surface and Invention VI does not require this limitation. Invention IV involves sequestering the conjugates with a solid support and Invention VI does not require this limitation. Invention VI involves generating a signal from the peptides bound to the probe and invention IV does not require this limitation.

22. Inventions IV and VII are independent and distinct inventions. Invention IV involves at least one protease bound to a solid surface and Invention VII does not require this limitation. Invention VII involves a second complex protein mixture with a second activity based probe and Invention IV does not require this limitation.

23. Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as

claimed can be used in a materially different process such as the process of Inventions I, II or III.

24. Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as the process of Inventions I, II or III.

25. Inventions V and VIII are independent and distinct inventions. Invention V is a kit comprising a plurality of affinity based labeled probes comprising a ligand, at least one protease, and a protein standard whereas Invention VIII is a method of correlating a separation profile. The two inventions are not disclosed as capable of use together.

26. Inventions VI and VII are independent and distinct inventions. Invention VII involves a second complex protein mixture with a second activity based probe and comparing a first signal generated to a second signal generated and Invention VI does not require these limitations.

27. Inventions VI and VIII are independent and distinct inventions. Invention VI involves proteolyzing the active target proteins and Invention VIII does not require this limitation. Invention VIII involves generating a separation profile and Invention VI does not require this limitation.

28. Invention VII and Invention VIII are independent and distinct inventions.

Invention VII involves a second complex protein mixture with a second activity based probe and also involves proteolyzing the active target proteins and Invention VIII does not require these limitations. Invention VIII involves generating a separation profile and Invention VII does not require this limitation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for one group is not required for other restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

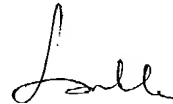
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary W. Counts
Examiner
Art Unit 1641
June 29, 2004



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07/07/04